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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/638,215	08/07/2003	Rebecca Gottlieb	047711-0316	3315
23392	7590 07/19/2006		EXAM	INER
FOLEY & LARDNER			GRAY, PHILLIP A	
2029 CENTURY PARK EAST			<u> </u>	
SUITE 3500			ART UNIT	PAPER NUMBER
LOS ANGELE	ES, CA 90067		3767	

Please find below and/or attached an Office communication concerning this application or proceeding.

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		Application No.	Applicant(s)			
Office Action Summary		10/638,215	GOTTLIEB ET AL.			
		Examiner	Art Unit			
		Phillip Gray	3767			
Period fo	- The MAILING DATE of this communication ap r Reply	pears on the cover sheet	with the correspondence address			
WHIC - Exten after S - If NO - Failur Any re	DRTENED STATUTORY PERIOD FOR REPL HEVER IS LONGER, FROM THE MAILING D sions of time may be available under the provisions of 37 CFR 1. SIX (6) MONTHS from the mailing date of this communication. period for reply is specified above, the maximum statutory period e to reply within the set or extended period for reply will, by statuted ply received by the Office later than three months after the mailing d patent term adjustment. See 37 CFR 1.704(b).	OATE OF THIS COMMUN 136(a). In no event, however, may will apply and will expire SIX (6) M te, cause the application to become	NICATION. a reply be timely filed  ONTHS from the mailing date of this communication. ABANDONED (35 U.S.C. § 133).			
Status						
1)⊠	Responsive to communication(s) filed on 18 h	<i>May 2006</i> .				
2a) <u></u> ☐	This action is FINAL. 2b)⊠ This action is non-final.					
•	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under	Ex parte Quayle, 1935 C	.D. 11, 453 O.G. 213.			
Dispositi	on of Claims					
4)⊠	☑ Claim(s) <u>1-48</u> is/are pending in the application.					
4	4a) Of the above claim(s) 24-48 is/are withdrawn from consideration.					
5)	Claim(s) is/are allowed.					
·	Claim(s) <u>1-23</u> is/are rejected.	·	•			
•	Claim(s) is/are objected to.					
8)	Claim(s) are subject to restriction and/	or election requirement.				
Application	on Papers					
9) 🔲 -	The specification is objected to by the Examin	er.				
10) 🔲 🗀	Γhe drawing(s) filed on is/are: a) ☐ ac	cepted or b) Objected	o by the Examiner.			
	Applicant may not request that any objection to the	•				
	Replacement drawing sheet(s) including the correct					
11)[	The oath or declaration is objected to by the E	xaminer. Note the attacr	led Office Action or form P1O-152.			
Priority u	nder 35 U.S.C. § 119					
•	Acknowledgment is made of a claim for foreig ☐ All b) ☐ Some * c) ☐ None of: 1. ☐ Certified copies of the priority documer		§ 119(a)-(d) or (f).			
	2. Certified copies of the priority documer	nts have been received in	Application No			
	3. Copies of the certified copies of the price	•	en received in this National Stage			
	application from the International Burea					
* S	ee the attached detailed Office action for a lis	it of the certified copies n	ot received.			
Attachmen	i(s)					
1) Notic	e of References Cited (PTO-892)		w Summary (PTO-413)			
3) 🛛 Inform	e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08 r No(s)/Mail Date <u>1/5/2005</u> .		No(s)/Mail Date of Informal Patent Application (PTO-152)			

### **DETAILED ACTION**

This Office Action is in response to applicant's communication of 5/18/2006.

Currently elected claims 1-23 are pending and rejected. Claims 24-48 are cancelled.

#### Election/Restrictions

Applicant's election of claims 1-23 in the reply filed on 5/18/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's election without traverse of Claims 1-23 in the reply filed on 5/18/2006 is acknowledged.

Claims 24-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/18/2006.

#### Claim Objections

Claim 14 is objected to because of the following informalities: Claim 14 depends from claim 11, and such claim limitation makes no reference of an analyte and lacks antecedent basis. It is likely applicant meant claim 14 to depend from claim 12 or claim 13, not claim 11. The claim is unclear as stands pending. Appropriate correction is required.

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## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11,14-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Barry (U.S. Patent Application Number US2002/0077592 A1). Barry discloses a replenishable stent and drug delivery system (see figures 1-16 and paragraphs at [0002]-[0048] generally, specific embodiments at [0067]-[0097]). Barry discloses a method for mitigating restenosis at a trauma site (where a stent is located) within the vasculature comprising: positioning a balloon catheter adjacent, interior to the stent, before or after a stent procedure, at a trauma site; and delivering a restenosis mitigating drug through apertures in the balloon catheter, upstream to the trauma site. Barry discloses the balloon catheter abuts a wall of the vasculature at the trauma site after the balloon catheter is expanded and also adjusting the flow rate and dispersal pattern of the restenosis mitigating drug. Barry further discloses using a restenosis mitigating agent or drug, which would include the use of insulin, nitric oxide, antibody, steroid, interleukin, blood thinner, ect. (see paragraph [0075]).

Claims 4, and 12-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Silver (U.S. Patent Number 6,442,413). Silver discloses an implantable glucose sensor that can be used for implantation in a blood vessel. Silver discloses a method where

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the delivery of the restenosis mitigating drug is modified in response to the sensing of analyte or glucose (see paragraphs beginning at column 6 line 65)

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry. Barry discloses the claimed invention except for the specific mention of using the specific drugs. Examiner believes these drugs to be implicitly stated in the Barry reference and thus an appropriate 102 rejection. However if not directly disclosed in Barry, they are obvious. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a restenosis mitigating drug of insulin,

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nitric oxide, antibody, steroid, interleukin, blood thinner, ect, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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> KEVIN C. SIRMONS SUPERVISORY PATENT EXAMINER

Kevin C. Sermons